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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,014	06/27/2003	Robert Andrew Badley	ISA-002.01	8357
63767	7590	07/17/2006		
FOLEY HOAG, LLP PATENT GROUP, (w/INVERNESS 155 SEAPORT BLVD. BOSTON, MA 02210-2600			EXAMINER RAMILLANO, LORE JANET	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/609,014	<b>Applicant(s)</b> BADLEY ET AL.	
	<b>Examiner</b> Lore Ramillano	<b>Art Unit</b> 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 6/2/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 37-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/2/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Election/Restrictions**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-36, drawn to an assay reader for determining the presence of a luminescent label in the capture zone of an assay device, classified in class 436, subclass 172.
  - II. Claims 37-40, drawn to a method of determining the presence of a luminescent label in the capture zone of an assay device, classified in class 436, subclass 546.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practiced by another and materially different apparatus, such as an apparatus that does not have a positioning member to hold the assay device in a reading position.
3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with Jennifer Zarutskie on 4/21/06 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-36.

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Affirmation of this election must be made by applicant in replying to this Office action.

Claims 37-40 are withdrawn from further consideration by the examiner, 37

CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Drawings**

6. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following claimed limitations: "aperture," "mouth of the recess," "first shape," and "second shape," must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### **Claim Objections**

7. Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 8 does not further limit claim 7 because the "window" is also located in the assay device, and thus claim 8 is broadening rather than further limiting the scope of claim 7.

8. Claim 15 is objected to because the claim should be amended accordingly: "wherein said window [comprises] is an aperture in said housing."

9. Claim 33 is objected to because of the following informality: Claim 33 contains a backslash "/" at the end of the claim. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 10, 15, 16, 18, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 10 is rejected because the following language is unclear: "first and second filters can be exchanged between a first configuration." What does applicant mean by the term "exchanged"?

Claims 15 and 16 are rejected because it is unclear how "aperture" and "recess" can be considered different terms in this context? If recess is not an aperture, then how can it be a window? The examiner will interpret the "aperture" and the "mouth of the recess" to represent the same limitation.

Claim 18 is rejected because the following language is unclear: "shaped to adapt the image." Is the image always the same? The examiner will interpret this claim in light of the structural elements that are disclosed and not for their intended use as stated after the term "to adapt," which is an intended use language.

Claim 20 is rejected because the following language is unclear: "emission from the first label is adapted into a first shape and emission from the second label is adapted into a second shape." What specifically does applicant mean by "shape"? The examiner will interpret this claim in light of the structural elements that are disclosed and not for their intended use as stated after the term "adapted into," which is an intended use language.

### **Claim Rejections - 35 USC § 102**

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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13. **Claims 1, 2, 15-21, 23-32, 35, and 36** are rejected under 35 U.S.C. 102(b) as being anticipated by Catt et al. ("Catt," US 6235241).

Catt disclose an assay reader comprising: a positioning member (recess, 401, Fig. 4a); a light source (ie. ultra-violet light source, 303, Fig. 3); a first viewing window (aperture, 205, Fig. 2); a second viewing window (209, Fig. 2); and lens (column 2, lines 27-32).

Catt further disclose that the light source is contained in a housing, and the assay device is also contained in the housing (Figs. 2 and 3).

Catt further disclose a light source (303) that produces an excitation signal (ultra-violet light, first mode, column 4, lines 33-53; column 5, lines 38-45).

Catt further disclose capture zones (reaction zones, 102, 103, Fig. 1), which are the zones that are used to detect for the presence of first and second labels (column 7, line 55-100; column 8, lines 35-50). Additionally, Catt disclose the limitations recited in claim 14 since this claim contains intended use language ("adapted to") and thus, the examiner will interpret this claim in light of the structural elements that are disclosed and not for their intended use as stated after the term "adapted into."

Catt further disclose that the window (205) comprises a non-reflective surface (light is able to pass through the window, column 9, lines 43-59).

Catt further disclose a battery connected to the light source and circuitry (430, Fig. 4b). (column 11, line 59 to column 12, line 1-36).

Catt further disclose that the reader and assay device may either be separable or non-separable (column 3, line 63 to column 4, line 5).

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Catt further disclose a control indicator or other indicators (ie. LED, electrochromic, or fluorescent dye) on the outer surface of the reader (column 11, line 35 to column 12, line 15).

### **Claim Rejections - 35 USC § 103**

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).



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17. **Claims 3-14, 22, and 33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Catt in view of Hubscher et al. ("Hubscher," US 6824975).

Catt does not specifically disclose a filter, a wavelength of the emission signal, a fluorescent label, and a lateral flow assay device.

Hubscher disclose a lateral flow assay device comprising a filter, different wavelengths of the emission signal, and fluorescent labels (column 6, lines 12-38).

Catt and Hubscher are analogous art because they are from the same field of endeavor, an assay device for detecting the presence of human bodily fluids. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Catt with the filter and wavelength limitations of Hubscher, as stated above, because it is well known in the art that fluorescent spheres, which are analytes attached to fluorescent microspheres or microparticles, are typically detected by a fluorescent reader that excites molecules at one particular wavelength (ie. 526nm) and detects the emission of the fluorescent waves at another wavelength (ie. 574nm). Additionally, it is known in the art to use an appropriate emission filter with a fluorescent reader. (Hubscher, column 6, lines 12-38).

It would have been obvious to a person of ordinary skill in the art to modify Catt by including two different filters because when using two different fluorescent labels to react with analytes, it would be essential to have two different filters to detect for two different emission signals.

With regard to the lateral flow immunoassay device, it would have been obvious to a person of ordinary skill in the art to use a lateral flow immunoassay device because

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these particular types of devices have the unique advantage of distinguishing at least three classes of antibodies and it is known in the art that lateral flow immunoassays that detect for fluorescent microparticles require the use of a reflectance reader, an excitation source (HeNe, Argon, tungsten or diode laser), and an appropriate emission filter for detection. (Hubscher, column 3, lines 38-43; column 6, lines 12-38).

18. **Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Catt in view of Greenquist et al. ("Greenquist," US 6824975).

Catt does not specifically disclose a homogenous assay device.

Greenquist disclose a homogenous specific binding assay device (ie. test strip) for determining a ligand (ie. antibody) in a liquid sample. (abstract).

Catt and Greenquist are analogous art because they are from the same field of endeavor, an assay device for detecting the presence of human bodily fluids. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Catt by using specifically a homogenous assay device of Hubscher, as stated above, because homogenous specific binding assay devices provide great advantages to the routine user of such assay devices, whereby the determining of ligands appearing in very low concentrations in liquid samples would be simplified to the steps of contacting the device with the sample and measuring the resulting signal either by visual observation or by instrumental means. (Hubscher, column 3, lines 26-38). In addition, it is well known in the art that the detectable product of a homogenous specific binding assay system is preferably a fluorescent molecule. (Hubscher, column 6, lines 12-38).

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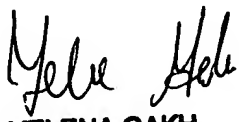
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri., from 10am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano  
Examiner  
Art Unit 1743

6/28/06

  
**YELENA GAKH**  
**PRIMARY EXAMINER**